

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

PrXELODA[®]

capecitabine tablets

Tablets 150 mg and 500 mg

Manufacturer's Standard

Antineoplastic Agent

Hoffmann-La Roche Limited
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Mississauga, Ontario
L5N 5M8

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrXELODA®
capecitabine tablets

Read this carefully before you start taking **PrXELODA®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PrXELODA®**.

Serious Warnings and Precautions

Serious side effects include:

- **Severe dehydration** may cause rapid loss of kidney functions including kidney failure. This may lead to death.
- Sudden death due to **heart problems** including irregular heartbeat.
- **Severe skin reactions** such as hand-and foot syndrome, Stevens-Johnson Syndrome [SJS] and Toxic Epidermal Necrolysis [TEN].
- **Severe toxicity including death in patients who do not have an enzyme called dihydropyrimidine dehydrogenase (DPD)**. If you lack this enzyme you should not take XELODA. Your healthcare professional might check to see if you have this enzyme before you can take XELODA.
- **Increased bleeding** in patients also taking medicines that thin the blood. This can happen as soon as a few days after you start taking XELODA. It can also happen later during treatment and possibly even within 1 month after you stop taking XELODA. Before you start taking XELODA, tell your healthcare professional if you are also taking a blood thinner medicine, like warfarin. Your doctor might check the clotting time of your blood before you take XELODA and while you are taking it.

See “Serious side effects and what to do about them” table for more information.

What is XELODA used for?

XELODA is used to treat patients with:

- Stage III colon cancer (Duke's stage C) which is a condition where the cancer of the colon has spread to other areas. It is used after surgery has been performed.
- Cancer of the colon or rectum that is called metastatic. Metastatic means the cancer has spread to other parts of the body.
- Metastatic cancer of the colon or rectum in combination with another cancer medicine called oxaliplatin. In these patients, it is used after another medicine called irinotecan was tried previously.
- Breast cancer that is advanced or metastatic after therapy with other medicines has not worked.
- Breast cancer that is advanced or metastatic in combination with another cancer medicine called docetaxel. In these patients it is used when other medicines have not worked.

How does XELODA work?

XELODA belongs to a family of medicines called fluoropyrimidines. These medicines interfere with the growth of cells that divide rapidly in the body like cancer cells. XELODA is converted to the medicine fluorouracil in the body. It prevents the growth of cancer cells and kills them.

What are the ingredients in XELODA?

Medicinal ingredients: capecitabine

Non-medicinal ingredients: croscarmellose sodium, hydroxypropyl methylcellulose, iron oxides (yellow and red), lactose anhydrous, magnesium stearate microcrystalline cellulose, talc, titanium dioxide.

XELODA comes in the following dosage forms:

As tablets containing 150 mg and 500 mg capecitabine.

Do not use XELODA if you:

- Are allergic to capecitabine, 5-fluorouracil.
- Are allergic to any of the other non-medicinal ingredients in XELODA.
- Have severe kidney problems.
- Have been told that you do not have an enzyme called dihydropyrimidine dehydrogenase (DPD).
- Are being treated now or have been treated in the last 4 weeks with brivudine, sorivudine or similar classes of medicines¹ as treatment for herpes zoster (chickenpox or shingles).

¹sorivudine and brivudine are not approved in Canada.

It is not known if XELODA is safe and effective in patients younger than 18 years of age

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take XELODA. Talk about any health conditions or problems you may have, including if you:

- Are allergic to other medications, food and dyes.
- Are taking phenytoin (Dilantin®) or fosphenytoin (Cerebyx®). Your doctor may need to check the levels of phenytoin in your blood more often.
- Are taking docetaxel.
- Have heart problems.
- Have liver problems.
- Have kidney problems.
- Are pregnant, plan to become pregnant or are breastfeeding or are planning to breastfeed.
- Are 60 years of age or older.

Other warnings you should know about:

- XELODA may impair fertility in females and males.
- **Female Patients:** You should not become pregnant while you are taking XELODA. This is because it can harm your unborn child. Before you start taking XELODA, it is recommended that you test to make sure you are not pregnant. You must use effective birth control while you are taking XELODA and for nine months after you stop taking it. Talk to your healthcare professional about effective methods of birth control.
- **Male Patients:** You should not father a child if you are taking XELODA. If your female partner is of childbearing age you must use effective birth control while you are taking XELODA and for 3 months after you stop taking it. Talk to your healthcare professional about effective methods of birth control for you and your partner.
- You should stop breastfeeding during treatment with XELODA and for 2 weeks after the final dose.
- If you are over 65 years old, you may be more sensitive to the toxic side effects of XELODA. Watch more carefully for possible diarrhea, nausea, and vomiting.
- If you experience persistent or severe hand-and-foot syndrome while taking XELODA, it can eventually lead to loss of fingerprints. This could impact your identification by fingerprint scan.
- **Driving and using machines:** XELODA may make you feel dizzy, nauseous or tired. This may affect your ability to drive a car or operate machines. Before driving or using machines, wait until you are feeling well again.
- **Your doctor may tell you to decrease the dose or stop XELODA treatment for a while if side effects appear.** If caught early, most of these side effects usually improve after you stop taking XELODA. If they do not improve within 2 to 3 days, call your doctor again. After side effects have improved, your doctor will tell you whether to start taking XELODA again and what is the right dose for you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XELODA:

- Medicine used to treat seizures such as phenytoin and posphenytoin.
- Blood thinner medicine such as warfarin and phenprocoumon.
- Medicine used to treat heartburn and acid indigestion such as Maalox®.
- Leucovorin, a medicine used to prevent the harmful effects of cancer chemotherapy medication.
- Certain medicines used specifically for treating viral infections such as sorivudine and brivudine.²

²sorivudine and brivudine are not approved in Canada.

How to take XELODA:

- Take XELODA exactly as your healthcare professional tells you to.
- Swallow tablets whole with water.
- Take XELODA within 30 minutes after finishing a meal.
- Do not crush or cut XELODA tablets.
- If you cannot swallow XELODA tablets, speak to your healthcare professional.
- Stay under your healthcare professional's care while taking XELODA.
- Your healthcare professional might change your dose or stop your treatment if you develop certain side effects.

Usual dose:

The usual dose of XELODA depends on your body surface size. Your healthcare professional will tell you how much XELODA to take.

You may need to take a combination of 150 mg and 500 mg tablets. **To get the right dose it is very important that you identify the tablets correctly each time you take XELODA.** Taking the wrong tablets could result in an overdose (too much medication) or underdose (too little medication).

Take the tablets twice a day (morning and evening doses) as your doctor prescribed. Do not take more than your prescribed dose, more often or for a longer time than your doctor told you to.

XELODA is taken in 21 day cycles. This means you take XELODA for 14 days and then stop taking it for 7 days. It is important to have this rest period. Your doctor will tell you how many cycles of treatment you will need.

For the treatment of colon cancer following complete surgical removal, XELODA is usually taken for eight 21-day cycles (i.e. for a total of 24 weeks or approximately 6 months).

Overdose:

If you think you, or a person you are caring for, have taken too much XELODA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget a dose of XELODA do not take the missed dose at all. Take your next dose at the usual time and check with your doctor. Do not take a double dose.

What are possible side effects from using XELODA?

These are not all the possible side effects you may have when taking XELODA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Constipation
- Skin irritation
- Fever
- Pins and needles sensation
- Loss of appetite
- Eye irritation
- Indigestion
- Heartburn
- Hair loss
- Taste altered
- Dizziness
- Nail changes, deformation, or abnormality
- Pain in limb
- Headache
- Trouble sleeping
- Muscle pain

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Diarrhea		✓	
Tiredness or fatigue		✓	
Nausea		✓	
Vomiting		✓	
Reduced white blood cell, red blood cells and platelets in the		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
blood: bleeding, bruising, chills, fatigue, fever, infections, weakness.			
Stomatitis (inflammation of the mouth, tongue and throat): sores, ulcers, redness, pain or swelling of the mouth including inside, the tongue or the throat, problems eating.		✓	
Hand-foot Syndrome: tingling, numbness, pain, swelling, redness or blisters of the palms of the hands or soles of feet.		✓	
COMMON			
Infection: cough, fever, pain during urination, sore throat		✓	
Increased chance of unusual bleeding		✓	
Dehydration: increased thirst, dry or sticky mouth, headache, less urination, dark yellow urine.		✓	
Heart problems: chest pain, abnormal heart rate, fainting, heart skipping a beat, shortness of breath, swelling of ankles or legs, weakness.		✓	
UNCOMMON			
Liver problems: abdominal pain, dark urine, fatigue, light-coloured stool, loss of appetite, nausea, vomiting, yellowing of the skin or eyes (jaundice).		✓	
Kidney problems: back and abdominal pain, change in the colour of urine, drowsiness, confusion or coma, fatigue, swelling of the legs and feet, nausea, vomiting, water retention, and weight gain.		✓	
VERY RARE			
Leukoencephalopathy (brain disease): lack of coordination or balance, loss of vision, personality or mood changes, trouble speaking, weakness.		✓	
UNKNOWN			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Angioedema (swelling in your body that is serious): swelling of face, lips, tongue, throat, eyes and/or mouth, hives, rash, voices changes, a harsh vibrating noise when breathing, severe difficulty breathing, fainting sensation or collapse.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Talk to your healthcare professional if you experience **any diarrhea, vomiting or nausea. Stop taking XELODA and call your doctor immediately if you notice any of the following additional symptoms in regards to your diarrhea, vomiting or nausea.** Your doctor can then adjust XELODA to a dose that is right for you. This should help to reduce the side effects and stop them from getting worse.

Diarrhea:

- an additional 4 bowel movements a day beyond what is normal or any diarrhea at night
- if you have a colostomy, an increase in loose, watery fluid in your colostomy bag
- any diarrhea together with soreness of the mouth affecting your ability to drink enough fluids

Vomiting:

- vomiting more than once in 24 hours, especially if you also have diarrhea

Nausea:

- loss of appetite or eating less food than usual each day

Side effects may differ when taking XELODA in combination with docetaxel compared with taking XELODA alone. In addition to the above side effects listed, increased tears, joint pain, muscle pain, and sore throat be occur. Talk to your doctor for more information on the possible side effects that may occur when taking XELODA in combination with docetaxel.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

Store at room temperature (15-30°C), in the original package.

Special handling using appropriate equipment and disposal procedures, should be taken as XELODA can be harmful to normal cells of the body. Any unused medicinal product or waste material should be disposed in accordance with local requirements.

If you want more information about XELODA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.rochecanada.com, or by calling 1-888-762-4388.

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